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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,676	08/16/2001	Donald E. Weaver	NCI-006DV2	5947

959 7590 10/04/2002

LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 10/04/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/932,676

Applicant(s)
Weaver et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 16, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-90 ☒ are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 2-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 2-90 are pending in this application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 2-12, drawn to a method for inhibiting epileptogenesis, classified in class 514, subclass various.
- II. Claims 13 and 16-21, drawn to a compound, composition and method of use, classified in class 564/514, subclass various.
- III. Claim 14, drawn to a method of use of a compound, classified in class 514, subclass various.
- IV. Claim 15, drawn to a method for inhibiting a convulsive disorder, classified in class 514, subclass various.
- V. Claims 23-32, 42, 43-45, 46 and 49, drawn to a dioxapiperazine compound, corresponding composition and method(s) of use, classified in class 544/514, subclass 358+/255.
- VI. Claims 34-41, drawn to another method of inhibiting convulsive disorder, classified in class 514, subclass various.
- VII. Claims 53-55, drawn to another method for inhibiting epileptogenesis, classified in class 514, subclass various.

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- VIII. Claims 50 and 52, drawn to a process of preparation, classified in class 564, subclass various.
- IX. Claim 51, drawn to another process of preparation of a compound of formula VIII, classified in class 560/562, subclass various.
- X. Claims 64-65, 66-67, 68-87 and 88-90 drawn to another method for inhibiting epileptogenesis, classified in class 514, subclass various.
- XI. Claims 56-57, drawn to another method for inhibiting epileptogenesis, classified in class 514, subclass various.
- XII. Claim 58, drawn to a method for inhibiting a neurological condition, classified in class 514, subclass various.
- XIII. Claims 59-63, drawn to a process for preparing a β -aryl- β -alanine compound, classified in class 564, subclass various.
- XIV. Claim 22, drawn to a kit for therapeutic use, classified in class 424, subclass various.
- XV. Claim 33, drawn to another kit for therapeutic use, classified in class 424, subclass various.
- XVI. Claim 48, drawn to another kit for therapeutic use, classified in class 424, subclass various.

The inventions are distinct, each from the other because of the following reasons:

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The inventions of Groups II and V are directed to structurally dissimilar compounds such that a reference compound which anticipates one of the groups would not make obvious the other groups. The groups of compounds are made and used independently.

Inventions I, III, VI, VII, X, XI and XII, that are drawn to methods for inhibiting epileptogenesis, etc., are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can also be used e.g., as a NMDA antagonist or endogenous GABA inhibitor.

Inventions II, V and XIV-XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are the compounds, compositions and method of use and a kit used for the dispersal of the composition.

Groups VIII-IX and XIII are drawn to various processes of preparation of structurally dissimilar compounds and are of different scope from that of the compounds of Groups II and V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II or viceversa, restriction for examination purposes as indicated is proper.

Further, **along with the election of a single group from above, election of a single species that falls within that group is also required**. Claims are generic to a plurality of disclosed patentably distinct species comprising the species disclosed in the examples. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Due to the lengthy and complex nature of the groups, the restriction requirement is set forth in writing.

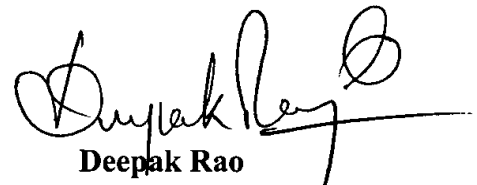
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Deepak Rao
Primary Examiner
Art Unit 1624

October 3, 2002